

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/349,925	07/08/99	CHANGEUX	J 3495.0135-02

HM12/1011

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EXAMINER

PARAS JR, P

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 10/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Advisory Action**

Application No.

09/349,925

Applicant(s)

CHANGEUX ET AL.

Examiner

Peter Paras, Jr.

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 30 August 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

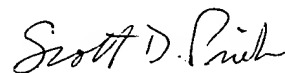
Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 40-58.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other:

Continuation of 5. does NOT place the application in condition for allowance because: The claims have not been amended and as filed the claims do not place the application in better form for appeal by materially reducing or simplifying the issues for appeal. First the rejection under 112, 1st paragraph is maintained because Applicants have not disclosed a particular phenotype resulting from expression of a transgene in a mouse. The state of the art as set forth in the Office action mailed on 6/6/01 on pages 2-5 and in the Office action mailed on 9/28/00 on pages 2-7 clearly teaches the unpredictability of a phenotype resulting from expression of a transgene. The phenotype resulting from expression of a transgene is directly dependent on the particular nucleotide sequence, operably linked to a specific promoter, encompassed within the transgene as well as the site of integration of the transgene. While one of skill would be able to make a transgenic mouse that expresses a transgene of interest, one of skill would not know how to use a transgenic mouse that lacks a corresponding phenotype. The issue is not the ability to create a transgenic mouse but rather whether the specification has taught a use for such a transgenic mouse in the absence of a recited phenotype. Screening transgenic mice to find a mouse that exhibits the desired phenotype is essentially trial and error and does not meet the "how to use" standard of 112, 1st paragraph when assessing whether or not it would require undue experimentation to make and use the claimed invention. In light of such, the specification has not taught how to use the claimed invention and therefore one of skill in the art would not know how to use the claimed transgenic mouse. See pages 2-5 of the Office action mailed on 6/6/01. Additionally, Applicants have asserted that the Examiner has not addressed the argument that Kappel, Cameroon, and Palmiter are outdated and do not represent the state of the art at the time of filing of the claimed invention. In response the Examiner maintains that these references do in fact reflect the state of the unpredictable nature of the art of transgenics. Applicants, in fact have not provided any evidence to the contrary, which reflects that the art of transgenics is predictable with respect to transgene expression. Applicants have also asserted that the Examiner has not provided any arguments which refute Applicants assertions that Camper and Aguzzi reflect the state of the art of transgenics at the time of filing of the claimed invention. Actually, Camper and Aguzzi have been addressed on pages 2-5, particularly on page 5, of the Office action mailed on 6/6/01. Camper and Aguzzi do not teach Applicant's particular transgenic construct or the resulting phenotype from expression of Applicants transgenic construct. In light of such, the teachings of Camper and Aguzzi do not provide any additional teachings or guidance to assist the skilled artisan in determining how to use the claimed invention. Claims 43-44 remain rejected under 112, 2nd paragraph for not pointing out and distinctly claiming the invention. In claim 43 it is not clear if the DNA in question is from a transgene or endogenous DNA. Claim 43 depends from claim 41, however claim 41 does not make such a distinction either as claim 41 does not address the DNA of the second mouse at all. The claim must clearly recite whether the DNA of the second mouse is endogenous or heterologous. See pages 5-6 of the Office action mailed on 6/6/01. The previous double patenting rejection is maintained for the reasons of record. See page 6 of the Office action mailed on 6/6/01.



SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER

# **Intervi w Summary**

Application No.

09/349,925

Applicant(s)

CHANGEUX ET AL.

Examiner

Peter Paras, Jr.

Art Unit

1632

All participants (applicant, applicant's representative, PTO personnel):

(1) Peter Paras, Jr.

(3) \_\_\_\_\_

(2) voice mail of Timothy Donaldson.

(4) \_\_\_\_\_

Date of Interview: 13 September 2001

Type: a) ☒ Telephonic b) ☐ Video Conference

c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.

If Yes, brief description: \_\_\_\_\_

Claim(s) discussed: \_\_\_\_\_

Identification of prior art discussed: \_\_\_\_\_

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

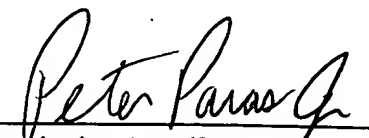
Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The Examiner left Applicant a voice message indicating that the amendment after final has been received and is under consideration

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) ☐ It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

  
Examiner's signature, if required